

K963398

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510(k) Summary

Proprietary Name: Alta® Fully Threaded Cross-Locking Screws

Common Name: Intramedullary Fixation Rod

Classification Name and Reference: 21 CFR 888.3020
Intramedullary Fixation Rod

Proposed Regulatory Class: Class II

Device Product Code: OR(87) HSB

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The Alta® Fully Threaded Cross-Locking Screws are intended to be used in conjunction with the Alta® Femoral and Alta® Tibial/Humeral Intramedullary Rod Systems. Specifically, the screws are used to lock the IM rods in position after placement in the femoral canal.

The fully threaded screws are manufactured from a Titanium alloy and are available in 5.0mm and 3.7mm diameters in lengths of 25 to 100mm.

The substantial equivalence of these screws is based on an equivalence in intended use, materials, design, operational principles, and relative indications and contraindications to Howmedica's Alta® Femoral Locking IM Rod System (K850441 & K922266), Alta® CFx Reconstruction Rod System (K926232, K935295 & K960524), and Alta® Tibial/Humeral IM Rod System (K884500, K890936 & K954554); Biomet's Uniflex Tibial Nail System and Retrograde Femoral Nail System; and Zimmer's ZMS Intramedullary Recon Nail.